

analyze data produced by an assay device, such as the lateral flow immunoassay cassette **105** (see FIG. 1).

[0058] While the testing apparatus **260**, is shown fitted to the handheld device **250**, one will appreciate that they testing apparatus can be configured as a separate unit that includes its own light source, power supply, optics, data capture capabilities, and the like. In such an embodiment, the testing apparatus may be configured to collect assay data from an assay cassette and transfer it (e.g., by a wired or wireless connection, by Bluetooth™, or the like) to the handheld device for analysis and reporting.

[0059] Referring now to FIG. 5A, FIG. 5A illustrates an exploded view of the diagnostic testing system **240** that is illustrated in FIGS. 4A and 4B. As can be seen in the exploded view, the testing apparatus **260** includes a main body housing **310** and an assay housing **320**.

[0060] The main body housing **310** is primarily designed to mate cleanly with the handheld device **250**. For example, the main body housing **310** may be shaped such that the handheld device **250** can be slid into the main body housing **310** such that the handheld device **250** clicks into or otherwise securely mates with the main body housing **310**. The main body housing **310** may also include one or more gaskets, seals, and the like that allow the handheld device to form a secure and light-tight seal with the main body housing **310**. Additional features of the main body housing **310** will be discussed below.

[0061] The assay housing **320** is fixedly coupled to the main body housing **310**. In the illustrated embodiment, the assay housing **320** includes a cassette port **270** that is configured such that a lateral flow immunoassay cassette **105** can be inserted into the assay housing **320**. In addition, the assay housing **320** in the in the illustrated embodiment includes a lens that is interposed between the handheld device's **250** back-directed camera (not shown) and the lateral flow immunoassay cassette **105**. Likewise, an optical fiber device or light pipe **340** that is capable of transmitting light either to the lateral flow immunoassay cassette **105** from the handheld device's **250** light source (not shown), from the lateral flow immunoassay cassette **105** to the handheld device's **250** back-directed camera (not shown), or both.

[0062] While the handheld device's **250** light source (not shown) can be used to illuminate the lateral flow immunoassay cassette **105**, the diagnostic testing system **240** may also include one or more additional light sources that can be housed in either the assay housing **320** or the main body housing **310**. Suitable examples of light sources can include, but are not limited to a camera flash, an autofocus illuminator on a camera, an LED light, an incandescent lamp, or a gas-discharge lamp. For example, the light source can come from micro-LED lamps that are included in the assay housing **320**. The micro-LEDs can be selected to emit certain wavelengths that are adapted for one or more assay conditions. The micro-LEDs can be powered by drawing electrical power from the battery of the handheld device **250**. In addition, either the assay housing **320** or the main body housing **310** may be configured such that ambient light or sunlight can be used to illuminate the lateral flow immunoassay cassette **105**.

[0063] In one embodiment, at least one wavelength filter may be interposed between the light source and the lateral-flow chromatographic immunoassay cassette **105**. For example, if the assay is a fluorescent assay, then the wavelength filter may be used to yield a specific wavelength of light from the light source to excite fluorescent emission from

the assay system. Likewise, certain colored dyes may yield a better signal when excited by selected wavelengths of light.

[0064] In one embodiment, the lens **330** (e.g., a collimating lens) may be used for focusing the light source on the lateral-flow chromatographic immunoassay cassette **105**. For example, the lens **330** may be used to increase the amount of incident light impinging on the lateral-flow chromatographic immunoassay cassette **105**. For instance, the purpose of the lens **330** may be to bring the focal point of the camera of the handheld device **250** (which is limited to about 6 inches or more) to less than 2 centimeters. This allows for a smaller overall package and produces a finer image that prevents the use of convoluting a blurry picture using Fourier transforms in order to produce a usable data that can be analyzed. Furthermore, with a multi-analyte detection assay (e.g., two calibration standard lines and a test sample line), the finer image will prevent overlap of the target lines to improve sensitivity and accuracy. In another example, a focusing apparatus may be used to focus ambient light or sunlight on the analysis zone of the lateral-flow chromatographic immunoassay cassette **105**.

[0065] In some embodiments, the assay cover **320** may include a device that can allow the angle of the lateral-flow chromatographic immunoassay cassette **105** to be adjusted relative to the handheld device **250** and a light source (not shown). By selectively modifying these angles, the lower detection limit of the assay can be extended, the signal to noise ratio can be improved, etc. In one embodiment, the device can be adjusted manually in order to choose an angle that optimizes detection limit, signal to noise, and the like. In another embodiment, the device can be coupled to a mechanical means, such as a servo motor or a gel-damped spring device that can allow the device to automatically sample a number of angles while the handheld device **250** collects data from the lateral-flow chromatographic immunoassay cassette **105**.

[0066] Referring now to FIG. 5B, the assay housing **320** and the cassette port **270** are illustrated in greater detail. In the embodiment illustrated in FIG. 3B, the cassette port **270** of the assay housing **320** includes a sealing gasket **350** disposed around the cassette port **270** that can seal the cassette port **270** when an assay cassette **105** is inserted therein so that ambient light does not leak into the housing **260**. For example, if ambient light leaks into the housing **260**, it could skew results. In addition, the cassette port **270** may include a spring-loaded flap (not shown) or similar means that can seal ambient light out of the housing **260** even when no cassette **105** is inserted into the cassette port **270**.

[0067] Referring now to FIGS. 6, 7A, and 7B, additional features of the housing **260** are illustrated.

[0068] Referring to FIG. 6, an example of an indexing feature that can reliably align the housing **260** relative to the handheld device **250** is illustrated. In the illustrated embodiment, the indexing feature may include a headphone jack **410** that is integrated into the housing body **310**. When the handheld device **250** is inserted into the housing body **310**, the headphone jack **410** is positioned such that it can be inserted into the headphone port **410** of the handheld device **250**. It will be understood by persons having ordinary skill in the art that headphone jack **410** is but one example of an indexing feature and that additional indexing features can be employed without departing from the spirit of this discussion.

[0069] In addition to aligning the housing body **310** relative to the handheld device **250**, the headphone jack **410** can be